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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,482

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EXAMINER

WEN, SHARON X

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,482	Applicant(s) LANE ET AL.	
	Examiner SHARON WEN	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 27-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-45 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I and species drawn to herpes viral infection in the reply filed on 10/15/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

Claims 27-45 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1-26 are currently under examination as they read on a method for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10 wherein the agent reads on an CXCL10 antibody.

Priority

3. The priority date for claims 1-26 is deemed the effective filing date of provisional application, USSN 60/456,028, i.e., 03/17/2003.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 12/21/2007 is acknowledged. However references CITE NOs. 3-89 have not been considered because Applicant has not provided copies of the reference.

Specification

5. Applicant is requested to review the application for spelling errors, use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademark is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Claim Rejections - 35 USC § 112 second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11-12 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present claims are indefinite in the recitation of “*fragment thereof*” because such limitation reads on any fragment of the antibody, including non-antigen binding fragment, e.g., Fc fragment. Therefore, one of skill in the art is not reasonably apprised of the metes and bounds of the antibody fragment.

Applicant is invited to amend the claim by reciting “antigen-binding fragment thereof” to obviate this rejection given there is sufficient written support in the specification as-filed.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al. (*Journal of Virology* 1996, 70:1277-1281, reference of record) in view of Liu et al. (*Journal of Immunology* 2001, 167:4091-4097, reference of record).

The present claims are drawn to a method for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10. Su et al. taught a method of treating ocular inflammation in subject with HSV-1 infection comprising administering a monoclonal antibody interocularly to mouse model of HSV-1 infection (see entire document, in particular, see page 1278, left column).

In particular, Su et al. taught a method to reduce ocular inflammation by reducing chemokine expression associated with HSV infection wherein CXCL-10 (aka. IP-10) was one the chemokines expressed during the infection (see page 1279, Figure 2 and last paragraph of left column).

Su et al. did not teach using an agent that specifically neutralizes CXCL-10 to reduce chemokine expression for treating ocular inflammation. However it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to use a neutralizing antibody specific for CXCL-10 because it was well known in the art that such anti-CXCL-10 antibody can neutralize CXCL-10 and reduce inflammation in other viral infected subjects as evidenced by Liu et al (see entire document, including Abstract and Discussion). In particular, Liu taught a neutralizing antibody to CXCL10 reduced the inflammation in a viral mouse model (see Results on pages 4093-4095).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use an anti-CXCL10 neutralizing antibody as taught by Liu et al to reduce ocular inflammation in subjects with herpes virus infection as taught by Su et al.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g, reducing ocular inflammation in herpes virus infection / neutralizing antibody to CXCL10) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (administering said neutralizing antibody to reduce ocular inflammation in herpes virus infection) with no change in their respective functions and the combination would have yielded nothing more than predictable results of reducing for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10.

Furthermore, the rationale to support a conclusion that the claims would have been obvious is that a particular known technique (administering a monoclonal antibody interocularly to reduce ocular inflammation in a subject with herpes virus infection) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known product (e.g. neutralizing anti-CXCL10 antibody) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

Although the teachings by Su and Liu were limited to mouse model, it would have been obvious to one of ordinary skill in the art to extrapolate the data from the mouse model to human therapy with reasonable expectation of success because of that a person of ordinary skill had good reason to pursue the known options (e.g. administration a monoclonal antibody interocularly to reduce ocular inflammation in a subject with herpes virus infection / reducing inflammation with a neutralizing antibody for CXCL10). This leads to the anticipated success of reducing for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10. It is likely the product not of innovation but of ordinary skill and common sense.

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

Given the combined teachings of Su and Liu rendered obvious of reducing ocular inflammation in a herpes infection, the same or nearly the same method would necessarily reduce the spread of the virus from cornea to retina or iris.

Given the above discussion, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/

Examiner, Art Unit 1644

December 30, 2008

/Phillip Gambel/

Primary Examiner

Technology Center 1600

Art Unit 1644

January 5, 2009